REMARKS

Status of the Claims

Claims 1-25 are pending in the application. We file this supplementary amendment to clarify the example embodiment of our previously filed response of April 19, 2010. Please consider the following.

Summary of Final Office Action dated November 18, 2009

In the office action, claim 22 is objected to because of an informality; claims 14 and 19-23 are rejected under 35 U.S.C. §112 as failing to particularly point out and distinctly claim the subject matter that the applicant regards as his invention; claims 1-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Charles et al. (WO 0238045, "Charles") in view of Lang et al. (U.S. Patent Publication No. 2003/0112921, " Lang ") and Mitton et al., "3D Reconstruction Method from Biplanar Radiography Using Non-stereocorresponding Points and Elastic Deformable Meshes" ("Mitton.")

Response

Claim Objections

The action objects to claim 22 because of informalities. The previous amendment corrected the language referred to in the action. Therefore, applicants respectfully request withdrawal of the objection to claim 22.

Claim rejections under 35 USC §112

Claims 14 and 19-23 stand rejected under 35 USC §112, first paragraph, as failing to particularly point out and distinctly claim the subject matter that the applicant regards as his invention. Claims 19 and 14 were amended to correct the rejected language.

Accordingly, it is respectfully submitted that the currently pending claims complies with 35 USC §112. Therefore, applicants respectfully request withdrawal of the 35 USC §112 rejections.

Claim rejections under 35 USC §103

Applicants respectfully traverse the rejection of claims 1-25 under 35 USC §103(a) as unpatentable over Charles in view of Lang and Mitton.

I. Amendment and example embodiment

Applicants previously amended the independent claims 1, 19 and 24 to clarify that the claimed "generic model" is produced prior to the introduction of the digitized radiological data from the scanned signals to the calculation means.

In particular, claim 1 has been previously amended to recite:

> 1. Method for radiographic imaging, comprising:
>
> (a) introducing, into calculation means, digitized radiological data from signals delivered by means of detection of X-rays and corresponding to pixels of an image of an anatomical part comprising an osseous body <u>having a three-dimensional shape</u> and scanned, in an incidence, with a beam of X-rays having an energy spectrum distributed about at least two energies, the digitized <u>radiological</u> data comprising, for each pixel, coordinates of the pixel in the image and absorptiometry values designed to calculate <u>a</u> ~~the~~ bone mineral density of the osseous body, in units of a surface area; and
>
> (b) determining <u>a</u> ~~the~~ value of a composite index using a processor of a radiographic image display device based on the digitized radiological data, and based on a three-dimensional generic model of said osseous body <u>produced prior to the introducing of the digitized radiological data from the scanned signals to the calculation means</u>.

Independent claims 19 and 24 were similarly amended. Therefore, arguments on behalf of claim 1 apply similarly to claims 19 and 24.

Embodiments of the claimed subject matter provide a safer method of diagnosing certain bone related pathologies by increasing the precision of measurements of bone mineral density while submitting a patient to relatively lower levels of irradiation.

In an example embodiment, a generic model of an object to be imaged is provided. A generic model comprises a priori knowledge about how the imaged object should look like. A radiation source emits two energy spectrums along a first incidence at an object of a patient that is to be observed, such as a vertebra, to produce a first two-dimensional radiographic

image, enabling to determine bone mineral density. If necessary, a second two-dimensional radiographic image is taken along a second incidence. These two images are calibrated.

The generic model is modified to be adapted to the patient during the imaging. This would provide a personalized model. For example, a technician may identify control markers that are visible and identifiable in both of the first and second two-dimensional radiographic images. These common markers (stereo-corresponding control markers C1-C6) can be used to position the generic model in a common reference system, to provide a personalized model of the object. These markers, as well as other markers (non-stereo corresponding control markers C7-C25) that are not common to the two images, may be used to produce the personalized model, for example by moving each common control marker of the generic model to its measured position, and by moving the other markers to join the origin of the two of their respective positions to minimize the global deformation of the generic model of the object that is to be observed. A composite index of the 3D-geometry and of the bone mineral density of the object can be calculated, for example as in paragraph 123 of the application specification.

For example, and as the examiner points out, paragraphs 92 and 94 of the application specification describes the generic model as corresponding to a specific specimen. In this case, the generic model is used in subsequent observations of the same object. For this purpose, the generic model is "generic" in the sense that it applies as a common basis for use in the calculation of the subsequent observations of the same specific specimen. The subsequent observations may be taken to determine if any degeneration has occurred since the time of any previous observation.

Alternatively, and as the examiner points out, paragraph 92 the application specification describes the generic model as a model that can be used to analyze an object that is similar to the object that was used to produce the generic model. In any case, the generic model is a model that is determined ***prior*** to subjecting a patient to another battery of x-rays. In this manner, the amount of radiation to which the patient is subjected is decreased. The cited references do not provide such a benefit. Moreover, Charles teaches away from the invention and the cited references, alone or in combination, do not describe or suggest every limitation of the independent claims.

I. The Rejection applies art that teaches away from the patent application

A reference teaches away when a person of ordinary skill in the art, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant.[1] Charles teaches away from determining the value of a composite index of the three-dimensional shape of the osseous body and of bone mineral density, based on digitized radiological data and on the generic model produced beforehand. Charles expressly teaches the use of obtaining more images to increase the accuracy of its resultant three-dimensional patient image that is obtained by using current radiological data only. In particular, Charles teaches using more images, taken along different incidences, such as using three, five, and seven images. Using more images that are obtained by using only current radiological data discourages one of ordinary skill in the art from the claimed subject matter that uses "three-dimensional generic model ... produced prior to the introducing of the digitized radiological data." Therefore, Charles teaches away from the claimed invention and thus cannot form the basis for a proper prima facie case of obviousness.

II. The Rejection Fails to Show Each and Every Element of the Claims at Issue in the Cited Art

1. Charles does not describe or suggest the recited "three-dimensional generic model."

The cited references, alone or in combination, do not describe or suggest, "a method for radiographic imaging comprising introducing... digitized radiological data... and determining a value of a composite index based on the digitized radiological data... and based on a three-dimensional generic model... produced prior to the introducing of the digitized radiological data."

The examiner asserts, at page 16 lines to 2-8 of the outstanding office action, that Charles at pages 3-5 Figs. 3, 7, and 8, and paragraphs 75, 77, 90-94 describes or suggests the claimed generic model. Applicants respectfully disagree. Charles does not describe or suggest the generic model of the osseous body produced beforehand. In fact, Charles constructs a 3-D representation of the individual bone, based on current imaging data only. The examiner refers to Fig. 10 of Charles. However, Fig. 10 of Charles fails to teach what is stored in the storage means in Charles. The examiner also refers to steps 352 to steps 370 of

[1] In re Gurley, 27 F.3d 551, 553 (Fed Cir. 1994.)

Fig. 3. However, these steps relate to digital radiographic data, but not to a three-dimensional generic model. The examiner also makes reference to steps 390 to 398 of Fig. 3. The step 390 is named "complete 3-D model of one or more bones." This step makes reference to the fact of completing a three-dimensional model from radiological data determined in the preceding steps (310-389.) This step does not refer to a three-dimensional generic model produced beforehand.

The examiner further makes reference to steps 806-810 of Fig. 8. Even though step 806 makes reference to a "3-D model of bone" of this figure, there is no indication that such "3-D model" will be a "3-D generic model produced beforehand." In fact, this 3-D model is the same completed model of step 390 of Charles, as shown in paragraph 92 at the last sentence of Charles: "step 398 is described in more detail below with reference to Fig. 8."

Charles generates a three-dimensional model of the bone, *solely* based on current radiological data obtained from the patient. To the contrary, the present invention uses a three-dimensional generic model of the bone, produced beforehand. Such a generic model could, for example, be produced in advance, by statistical analysis of many embodiments or, for example, be produced in advance by 3-D images of the patient, if such previous images exist (See paragraphs 92-94 of the application specification.) Contrary to the assertion of the examiner at page 2 of the outstanding office action, a generic model produced beforehand could correspond to a specific specimen, if such a specimen is sufficiently generic (this single specimen is however not necessarily the patient himself.) Thus, there is no contradiction between our definition of a generic model and the claim.

Using such a generic model produced beforehand enables the complementing of the information observed from the patient, without submitting the patient to additional radiation. If a previous 3-D image of the patient is already available, they could be used without additional radiation to the patient. If it is not available, it could be replaced by a statistical model.

To the contrary, even though Charles constructs a so-called "three-dimensional model" of the patient, it is solely based on few images. To increase the accuracy of the three-dimensional model in Charles, Charles describes a method of taking more images, along different incidences, such as three, five, seven images... (See section 77 of Charles.) Taking

more images along different incidences to increase the accuracy of the three-dimensional model does not amount to "determining a value of a composite index based on the digitized radiological data... and based on a three-dimensional generic model... produced prior to the introducing of the digitized radiological data." Therefore, Charles does not describe "determining a value of a composite index based on the digitized radiological data... and based on a three-dimensional generic model... produced prior to the introducing of the digitized radiological data."

2. Charles does not describe or suggest the recited "composite index."

As stated above, Charles does not teach the recited three-dimensional generic model that is produced beforehand. Further, Charles does not describe or suggest "a composite index ... based on the digitized radiological data, and based on a three-dimensional generic model of said osseous body produced prior to the introducing of the digitized radiological data."

The examiner refers to the abstract, and pages 3-5 of Charles, and in particular to the statement: "for computing principal moments of inertia and strength moduli of individual bone, plus risk of injury and changes in risk of injury of the patient." However, nothing in the whole Charles reference discloses that a calculation would provide a composite index of the shape 30 of the osseus body and of mineral density. The calculations of Charles can be performed based only on radiological images, without using the three-dimensional shape of the bone. The examiner refers to Fig. 3, steps 35-370 and 390-398, and to Fig. 8, steps 806-810. Step 398 is explained, at paragraph 92 of Charles as follows: "in step 398, estimates of risk of injury including risk of a bone breakage are computed. For example, estimates of mechanical strength scale for body size, gender and other factors are computed. In some embodiments, step 398 includes determining a spatial relationship between bones and metal objects implanted in the patient for repair or as prosthesis. Such spatial relationship may evidence separation and loosening of the metal object in any early stage before complete failure. Step 390 is described in more details below with reference to figure it." Therefore, step 398 gives two examples of calculation. First, the mechanical strength, which is not a composite index of the three-dimensional shape of the osseous body and a bone mineral density. Second, spatial relation between bones and metallic objects, to check whether there

is a risk of loosening. This also is not either a composite index of the three-dimensional shape of the osseous body and of bone mineral density.

Although paragraph 92 of Charles refers back to Fig. 8. Fig. 8 is no more explicit about the calculation of such a composite index. Paragraphs 147-150 of Charles do not describe any of the steps 390-398 of Fig. 8.

The examiner also refers to paragraph 91 of Charles, and in particular to the term "three-dimensional model" of this paragraph. As stated in paragraph 91, "from the principal moments of inertia, a three-dimensional model with patient specific mechanical properties is derived." This passage describes the obtaining of a three-dimensional model from principal moments of inertia, but does not describe the use of such a model to calculate a composite index, as claimed.

The examiner refers to paragraph 75, according to which "computer software is executed to form three-dimensional models of the bones, and to compute properties and risks of fracture based on the models." This sentence does not imply that such a composite index of the three-dimensional shape of the osseous body and of bone mineral density is calculated. Paragraphs 77, and 90 to 94, which are also referred to by the examiner, do not give any additional indication of calculate the recited composite index. The examiner also refers to Fig. 7. Although Fig. 7 describes some calculation made from images taken along different angles, Fig. 7 does not describe or suggest the claimed "a composite index ... based on the digitized radiological data, and based on a three-dimensional generic model of said osseous body produced prior to the introducing of the digitized radiological data." The independent claims are therefore novel in view of Charles, which is in fact not disputed by the examiner. Moreover, none of the cited references describe each and every element of the claims.

3. Lang and Mitton do not provide the features identified as missing in Charles.

Initially, the applicant reserves the right to show that Lang is not prior art to the present application.

Further, Lang and Mitton also do not provide the features identified as missing in Charles. Lang is purely *bi-dimensional* process. The examiner refers to paragraphs to 212 and 275 of Lang, which state "a general model of the proximal femur is created by manually *outlining* the shape in a training set of typical hip radiographs to form a mean shape."

Paragraph 275 of Lang also refers to Fig. 14 and is said to illustrate the propagation of initial control points to the edge of the femur. However, according to paragraph 46, Fig. 14 is related to a tooth rather than a femur. Nevertheless, a bi-dimensional outline does not amount to "three-dimensional generic model of said osseous body produced prior to the introducing of the digitized radiological data from the scanned signals to the calculation means."

Therefore, Lang does not describe a three-dimensional generic model produced beforehand, nor the calculation of the claimed composite index, in particular based on such a generic model. Further, the person having ordinary skill in the art at the time of the invention, who has a comprehensive understanding of the process in Charles, would not arbitrarily pick up from a very remote document, such as Lang, the steps needed to incorporate the process of Charles. According to the teaching of Charles, to improve the accuracy of the process, one should take more and more images along different angles. Lang does not redirect one of ordinary skill in the art away from the teaching of Charles, much less provide any way to remedy the deficiency of Charles, and particularly not in the way which is claimed.

Mitton is less relevant than Charles, because Mitten does not mention bone mineral density, nor the calculation of a composite index of the three-dimensional osseous body and of bone mineral density. Further, for the person skilled in the art at the time of the invention, it will be totally impossible to extract from Mitten some specific features to be introduced in the very comprehensive method used in Charles.

The present invention enables the calculation of the composition index of the three-dimensional shape of an osseous body and of bone mineral density, based on a three-dimensional generic model, produced beforehand, and based on digitized radiological data. This enables the use of fewer radiations to be performed on the patient to obtain a very accurate three-dimensional geometry of a bone of the patient, and not only projections of the bone and some specific planes. Thus, the accuracy of the prediction of a problem with the bone can be improved using embodiments of the invention. Such an increase of accuracy while decreasing radiation is of utmost importance for the persons who were suffering from bone disease, such as osteoporosis for example. None of the other cited documents hint toward the present invention.

Accordingly, the independent claims are not obvious in view of the cited references, nor are the dependent claims. Therefore, it is respectfully requested that the rejection of Claims 1-25 under 35 U.S.C. 103(a) as obvious over Charles, Lang, and Mitton be withdrawn.

Conclusion

In view of the above amendment and arguments, the applicant submits the pending application is in condition for allowance and an early action so indicating is respectfully requested. If there are matters that can be discussed by telephone to further the prosecution of this application, applicants respectfully request that the examiner call its attorneys at the number listed below.

The Commissioner is authorized to charge any fee deficiency required by this paper, or credit any overpayment, to Deposit Account No. 13-2855, under Order No. 28944/41376, from which the undersigned is authorized to draw.

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Respectfully submitted,

By____________________

Milena Sukovic
Registration No.: 60,532
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Willis Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant